K033067

NOV 26 2003

Summary of Safety and Effectiveness Information
H. pylori IgG ELISA Test Kit

I. Trinity Biotech
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Jamestown, NY 14701
Contact person: Bonnie B. DeJoy
Telephone: 716-483-3851
Date of preparation: Nov. 20, 2003

II. Description of Device

The H. pylori IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of IgG antibodies in human serum to antigen. The Trinity Pylori IgG ELISA assay may be used as an aid in the diagnosis of Helicobacter pylori infection in persons with gastrointestinal symptoms. **For In Vitro Diagnostic Use Only.**

The H. pylori IgG ELISA test is an enzyme linked immunosorbent assay to detect IgG antibodies to Helicobacter pylori. Purified Helicobacter pylori antigen is attached to a solid phase microtiter well. Diluted test sera is added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation, the wells are washed to remove unbound antibody. An enzyme labeled anti-human IgG is added to each well. If antibody is present it will bind to the antibody attached to the antigen on the well. After incubation, the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present, the substrate will undergo a color change. After an incubation period, the reaction is stopped and the color intensity is measured photometrically, producing an indirect measurement of specific antibody in the patient specimen.

III. Predicate Device

The H. pylori IgG ELISA test is substantially equivalent to biopsy. Equivalence is demonstrated by the following comparative results:

Performance Characteristics

A. Evaluation of Pylori IgG ELISA Sensitivity and Specificity Relative to Biopsy

The Trinity Biotech *H. pylori* IgG ELISA is a modification of Pylori Stat. Pylori Stat was originally evaluated by masked testing 386 serum from five geographically different areas, having biopsy with stain or culture results for *H. pylori*. The serum were from patients with random gender and various ages with the following clinical diagnoses: gastritis, gastric ulcer, duodenal ulcer, non-ulcer dyspepsia, esophagitis and normal. Table 1 illustrates the sensitivity and specificity of the Pylori Stat to biopsy.

Table 1
Pylori Stat IgG ELISA Sensitivity and Specificity

		Pylori Stat			
		+	eq	-	Total
biopsy*	+	261	12	4	277
	-	2	2	105	109
	Total	263	14	109	386

Sensitivity = 261/265 = 98.5% 95% Confidence interval = 97.0% - 100%
Specificity = 105/107 = 98.1% 95% Confidence interval = 95.5% - 100%
Agreement = 366/372 = 98.4% 95% Confidence interval = 97.1% - 99.7%

* Culture or stain
Equivocals were not included in the above calculations.
The 95% confidence intervals were calculated using the normal method.

The Trinity Biotech *H. pylori* IgG ELISA was evaluated by masked testing 371 serum from five geographically different areas, having biopsy with stain or culture results for *H pylori.* The serum were from patients with random gender and various ages with the following clinical diagnoses: gastritis, gastric ulcer, duodenal ulcer, non-ulcer dyspepsia, esophagitis and normal. Tables 2 and 3 illustrate the sensitivity and specificity of the Trinity Biotech *H. pylori* IgG ELISA to biopsy and the % agreement positive and % agreement negative of the Trinity Biotech *H. pylori* IgG ELISA to Biowhittaker Pylori Stat.

Table 2
Trinity Biotech *H. pylori* IgG ELISA Sensitivity and Specificity

		Trinity Biotech *H. pylori* IgG ELISA			
		+	eq	-	Total
biopsy*	+	244	13	9	266
	-	4	2	99	105
	Total	248	15	108	371

Sensitivity = 244/253 = 96.4%95% Confidence Interval = 94.1% - 98.8%
Specificity = 99/103 = 96.1% 95% Confidence Interval = 92.3% - 99.9%
Agreement = 343/356 = 96.4% 95% Confidence Interval = 94.4% - 98.3%

* Culture or stain
Equivocals were not included in the above calculations.
The 95% Confidence Intervals were calculated using the normal method.

Evaluation of Pylori IgG ELISA % Agreement Positive and % Agreement Negative Relative to Biowhittaker Pylori Stat

Table 3

Trinity Biotech *H. pylori* IgG ELISA

		+	eq	-	Total
	+	246	8	2	256
	eq	1	5	6	12
Biowhittaker Pylori Stat	-	3	3	97	103
	Total	250	16	105	371

% Agreement positive = 246/248 = 99.2% 95% Confidence Interval = 98.1% - 100%
% Agreement negative = 97/100 = 97.0% 95% Confidence Interval = 93.6% - 100%
% Agreement = 343/348 = 98.6% 95% Confidence Interval = 97.3% - 99.8%

Equivocals were not included in the above calculations.
The 95% Confidence Intervals were calculated using the normal method.

B. Precision

The precision of the Trinity Biotech *H. pylori* IgG ELISA was determined by testing six different sera ten times each on three days. The mean coefficients of variation from the intra- and inter- assays are presented in Table 6.

Table 4
Trinity Biotech *H. pylori* IgG ELISA Precision

	Assay 1 (n=10)			Assay 2 (n=10)			Assay 3 (n=10)			Inter-Assay (n=30)		
	X	SD	CV	X	SD	CV	X	SD	CV	X	SD	CV
1	3.13	0.209	6.68%	3.05	0.145	4.75%	3.13	0.210	6.71%	3.10	0.188	6.06%
2	2.08	0.151	7.26%	2.15	0.156	7.26%	2.01	0.127	6.32%	2.08	0.151	7.26%
3	2.31	0.258	11.2%	2.29	0.115	5.02%	2.24	0.173	7.72%	2.28	0.187	8.20%
4	1.17	0.184	15.7%	1.47	0.148	10.1%	1.30	0.179	13.8%	1.31	0.207	15.8%
5	0.06	0.018	30.0%	0.12	0.014	11.7%	0.11	0.056	50.9%	0.08	0.031	38.8%
6	0.10	0.016	16.0%	0.14	0.020	14.3%	0.10	0.067	67.0%	0.12	0.023	19.2%

C. Cross Reactivity

The Trinity Biotech *H. pylori* IgG ELISA ISR values were determined for paired sera from *C. jejuni* infections and single sera from *C. fetus* infections. The data in Table 7 shows no rise in antibody for *C. jejuni* paired sera, and negative responses for *C. fetus* infections indicating a lack of cross reactivity to these closely related organisms. Serum pairs 1, 2 and 3 demonstrate antibody to *H. pylori*. However, the pairs do not show a rise in antibody as would be expected in acute *C. jejuni* infection. Therefore, the response is considered to be specific for *H. pylori* with no cross reaction with *C. jejuni*. Sera positive

for *Borrelia burgdorferi* by ELISA and Western Blot were negative indicating a lack of cross-reactivity.

Table 5
Trinity Biotech *H. pylori* IgG ELISA Results with Potentially Cross-reactive Sera

Serum #	Diagnosis*	H. pylori IgG ISR
Acute 1	C. jejuni Diarrhea	2.30
Convalescent 1		2.41
Acute 2	C. jejuni Diarrhea	2.11
Convalescent 2		2.23
Acute 3	C. jejuni Diarrhea	1.23
Convalescent 3		1.20
Acute 4	C. jejuni Diarrhea	0.40
Convalescent 4		0.57
Acute 5	C. jejuni Diarrhea	0.88
Convalescent 5		0.89
6.	C. fetus Endocarditis	0.59
7.	C. fetus Endocarditis	0.63
8.	C. fetus Endocarditis	0.72
9.	C. fetus Bacteremia	0.38

*All cases diagnosed by culture; *C. jejuni* infection by fecal culture on *Camplylobacter*-specific media, *C. fetus* infection by blood culture.

10.	Borrelia burgdorferi	0.44
11.	Borrelia burgdorferi	0.20
12.	Borrelia burgdorferi	0.22
13.	Borrelia burgdorferi	0.89
14.	Borrelia burgdorferi	0.11
15.	Borrelia burgdorferi	0.20
16.	Borrelia burgdorferi	0.16
17.	Borrelia burgdorferi	0.59
18.	Borrelia burgdorferi	0.09
19.	Borrelia burgdorferi	0.13

All Borrelia burgdorferi sera were positive for antibodies by ELISA and Western Blot. Their clinical histories were suggestive of Lyme Disease.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 2003

Ms. Bonnie B. DeJoy
Director, Quality Systems
Trinity Biotech USA
P.O. Box 1059
Jamestown, NY 14702-1059

Re: k033067
Trade/Device Name: Captia H. Pylori IgG ELISA
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LYR
Dated: September 17, 2003
Received: September 29, 2003

Dear Ms. DeJoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K033067

Device Name: Trinity Biotech Captia™ H. pylori IgG ELISA

Indications For Use: The Trinity Biotech Captia™ H. pylori IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of IgG antibodies in human serum to *Helicobacter pylori*, as an aid in the diagnosis of *H. pylori* infection in adult patients with clinical signs and symptoms of gastrointestinal disease, and is not intended for use in asymptomatic patients.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 XFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

for FMP

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033067